

WHAT IS CLAIMED IS:

1. An aqueous formulation comprising:
an immune response modifier;
water; and
5 a hydrophilic viscosity enhancing agent;
with the proviso that the hydrophilic viscosity enhancing agent is not covalently bonded to the immune response modifier;
wherein the formulation is a solution at room temperature and has a viscosity of less than 100 cps at room temperature.
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2. The aqueous formulation of claim 1 wherein the immune response modifier is a positively charged immune response modifier.
3. The aqueous formulation of claims 1 or 2 wherein the hydrophilic
15 viscosity enhancing agent is negatively charged.
4. The aqueous formulation of any one of claims 1 through 3 wherein the hydrophilic viscosity enhancing agent is uncrosslinked.
- 20 5. The aqueous formulation of any one of claims 1 through 4 wherein the hydrophilic viscosity enhancing agent is selected from the group consisting of cellulose ethers, polysaccharide gums, acrylic acid polymers, and combinations thereof.
- 25 6. The aqueous formulation of claim 5 wherein the hydrophilic viscosity enhancing agent comprises carboxylic acid groups and/or carboxylate groups.
7. The aqueous formulation of claim 6 wherein the hydrophilic viscosity enhancing agent is selected from the group consisting of a acrylic acid polymer,
30 carboxymethyl cellulose sodium, xanthan gum, and combinations thereof.
8. The aqueous formulation of any one of claims 1 through 7 wherein the hydrophilic viscosity enhancing agent is present in an amount of at least 0.01 wt-%, based on the total weight of the formulation.

9. The aqueous formulation of any one of claims 1 through 8 wherein the immune response modifier is present in an amount of at least 0.0001 wt-%, based on the total weight of the formulation.

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10. The aqueous formulation of any one of claims 1 through 9 wherein the immune response modifier is present in an amount of at most 5.0 wt-%, based on the total weight of the formulation.

10 11. The aqueous formulation of any one of claims 1 through 10 wherein the immune response modifier is a compound having a 2-aminopyridine fused to a five membered nitrogen-containing heterocyclic ring.

12. The aqueous formulation of claim 11 wherein the immune response
15 modifier is selected from the group consisting of imidazoquinoline amines, tetrahydroimidazoquinoline amines, imidazopyridine amines, 6,7-fused cycloalkylimidazopyridine amines, 1,2-bridged imidazoquinoline amines, imidazonaphthyridine amines, imidazotetrahydronaphthyridine amines, oxazoloquinoline amines, thiazoloquinoline amines, oxazolopyridine amines,
20 thiazolopyridine amines, oxazonaphthyridine amines, thiazolonaphthyridine amines, 1*H*-imidazo dimers fused to pyridine amines, quinoline amines, tetrahydroquinoline amines, naphthyridine amines, or tetrahydronaphthyridine amines, and combinations thereof.

25 13. The aqueous formulation of claim 12 wherein the immune response modifier is selected from the group consisting of imidazoquinoline amines, tetrahydroimidazoquinoline amines, imidazopyridine amines, and combinations thereof.

30 14. The aqueous formulation of claim 13 wherein the immune response modifier is selected from the group consisting of amide substituted imidazoquinoline amines, sulfonamide substituted imidazoquinoline amines, urea substituted imidazoquinoline amines, aryl ether substituted imidazoquinoline amines, heterocyclic ether substituted imidazoquinoline

- amines, amido ether substituted imidazoquinoline amines, sulfonamido ether substituted imidazoquinoline amines, urea substituted imidazoquinoline ethers, thioether substituted imidazoquinoline amines, 6-, 7-, 8-, or 9-aryl or heteroaryl substituted imidazoquinoline amines, amide substituted
- 5 tetrahydroimidazoquinoline amines, sulfonamide substituted tetrahydroimidazoquinoline amines, urea substituted tetrahydroimidazoquinoline amines, aryl ether substituted tetrahydroimidazoquinoline amines, heterocyclic ether substituted tetrahydroimidazoquinoline amines, amido ether substituted tetrahydroimidazoquinoline amines, sulfonamido ether substituted
- 10 tetrahydroimidazoquinoline amines, urea substituted tetrahydroimidazoquinoline ethers, thioether substituted tetrahydroimidazoquinoline amines, amide substituted imidazopyridine amines, sulfonamide substituted imidazopyridine amines, urea substituted imidazopyridine amines, aryl ether substituted imidazopyridine amines, heterocyclic ether substituted imidazopyridine amines,
- 15 amido ether substituted imidazopyridine amines, sulfonamido ether substituted imidazopyridine amines, urea substituted imidazopyridine ethers, thioether substituted imidazopyridine amines, and combinations thereof.

15. The aqueous formulation of claim 14 wherein the immune response
- 20 modifier is selected from the group consisting of amide substituted imidazoquinoline amines, sulfonamide substituted imidazoquinoline amines, urea substituted imidazoquinoline amines, thioether substituted imidazoquinoline amines, 7-aryl substituted imidazoquinoline amines, 7-heteroaryl substituted imidazoquinoline amines, sulfonamide substituted
- 25 tetrahydroimidazoquinoline amines, and combinations thereof.

16. The aqueous formulation of claim 15 wherein the immune response modifier is a sulfonamide substituted imidazoquinoline amine.

- 30 17. The aqueous formulation of claim 15 wherein the immune response modifier is selected from the group consisting of:
- N^1 -{4-[4-amino-2-(2-methoxyethyl)-6,7,8,9-tetrahydro-1*H*-imidazo[4,5-*c*]quinolin-1-yl]butyl}-4-fluoro-1-benzenesulfonamide,

- N-[3-(4-amino-2-butyl-1*H*-imidazo[4,5-*c*]quinolin-1-yl)propyl]morpholine-4-carboxamide,
- N-{3-[4-amino-2-(2-methoxyethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-2,2-dimethylpropyl}-N'-phenylurea,
- 5 N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide,
- 2-butyl-1-[2-(propylsulfonyl)ethyl]-1*H*-imidazo[4,5-*c*]quinolin-4-amine,
- N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}-2-ethoxyacetamide,
- 10 N-{4-[4-amino-2-(cyclopropylmethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]butyl}methanesulfonamide,
- N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}-N'-cyclohexylurea,
- N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-
- 15 dimethylethyl}cyclohexanecarboxamide,
- N-{2-[4-amino-2-(ethoxymethyl)-6,7,8,9-tetrahydro-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide,
- N-[3-(4-amino-2-butyl-1*H*-imidazo[4,5-*c*]quinolin-1-yl)-2,2-dimethylpropyl]methanesulfonamide,
- 20 N-[2-(4-amino-2-butyl-1*H*-imidazo[4,5-*c*]quinolin-1-yl)-1,1-dimethylethyl]methanesulfonamide,
- N-{2-[4-amino-2-(2-methoxyethyl)-6,7,8,9-tetrahydro-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide,
- 1-[4-amino-7-(5-hydroxymethylpyridin-3-yl)-2-(2-methoxyethyl)-1*H*-
- 25 imidazo[4,5-*c*]quinolin-1-yl]-2-methylpropan-2-ol,
- 1-[4-amino-7-(3-hydroxymethylphenyl)-2-(2-methoxyethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-2-methylpropan-2-ol,
- N-{3-[4-amino-1-(2-hydroxy-2-methylpropyl)-2-(methoxyethyl)-1*H*-imidazo[4,5-*c*]quinolin-7-yl]phenyl}methanesulfonamide,
- 30 {5-[4-amino-2-(2-methoxyethyl)-1-(2-methylpropyl)-1*H*-imidazo[4,5-*c*]quinolin-7-yl]pyridin-3-yl}methanol,
- 1-[4-amino-2-(ethoxymethyl)-7-(pyridin-3-yl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-2-methylpropan-2-ol,

- 1-{4-amino-2-(ethoxymethyl)-7-[5-(hydroxymethyl)pyridin-3-yl]-1*H*-imidazo[4,5-*c*]quinolin-1-yl}-2-methylpropan-2-ol,
 N-(2-{4-amino-2-ethoxymethyl-7-[6-(methanesulfonylamino)hexyloxy]-1*H*-imidazo[4,5-*c*]quinolin-1-yl}-1,1-dimethylethyl)methanesulfonamide,
 5 N-(6-{[4-amino-2-ethoxymethyl-1-(2-methanesulfonylamino-2-methylpropyl)-1*H*-imidazo[4,5-*c*]quinolin-7-yl]oxy}hexyl)acetamide,
 N-[2-(4-amino-2-ethoxymethyl-1-propyl-1*H*-imidazo[4,5-*c*]quinolin-7-yloxy)ethyl]methanesulfonamide,
 1-[4-amino-2-(ethoxymethyl)-7-(1*H*-pyrazol-4-yl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-2-methylpropan-2-ol,
 10 3-[4-amino-2-(ethoxymethyl)-7-(pyridin-3-yl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]propane-1,2-diol,
 and combinations thereof
- 15 18. The aqueous formulation of claim 17 wherein the immune response modifier is selected from the group consisting of:
 N-[3-(4-amino-2-butyl-1*H*-imidazo[4,5-*c*]quinolin-1-yl)propyl]morpholine-4-carboxamide,
 N-{3-[4-amino-2-(2-methoxyethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-2,2-dimethylpropyl}-*N'*-phenylurea,
 20 N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide,
 2-butyl-1-[2-(propylsulfonyl)ethyl]-1*H*-imidazo[4,5-*c*]quinolin-4-amine,
 N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}-2-ethoxyacetamide,
 25 N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}-*N'*-cyclohexylurea,
 N-{2-[4-amino-2-(ethoxymethyl)-6,7,8,9-tetrahydro-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide,
 30 N-[2-(4-amino-2-butyl-1*H*-imidazo[4,5-*c*]quinolin-1-yl)-1,1-dimethylethyl]methanesulfonamide,
 N-{2-[4-amino-2-(2-methoxyethyl)-6,7,8,9-tetrahydro-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide,

- 1 - {4-amino-2-(ethoxymethyl)-7-[5-(hydroxymethyl)pyridin-3-yl]-1*H*-
imidazo[4,5-*c*]quinolin-1-yl}-2-methylpropan-2-ol,
N-(6-{[4-amino-2-ethoxymethyl-1-(2-methanesulfonylamino-2-methylpropyl)-
1*H*-imidazo[4,5-*c*]quinolin-7-yl]oxy}hexyl)acetamide,
5 and combinations thereof.

19. The aqueous formulation of claim 18 wherein the immune response
modifier is N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-
1,1-dimethylethyl}methanesulfonamide.

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20. The aqueous formulation of claim 11 wherein the immune response
modifier is a salt of an acid selected from the group consisting of a carboxylic
acid, a halo acid, sulfuric acid, phosphoric acid, dicarboxylic acid, tricarboxylic
acid, and combinations thereof.

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21. The aqueous formulation of claim 20 wherein the salt of the immune
response modifier is a salt of an acid selected from the group consisting of
hydrobromic acid, hydrochloric acid, lactic acid, glutamic acid, gluconic acid,
tartaric acid, succinic acid, and combinations thereof.

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22. The aqueous formulation of any one of claims 1 through 21 having a pH
of at least 4.

23. The aqueous formulation of claim 22 having a pH of no more than 8.

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24. The aqueous formulation of any one of claims 1 through 23 further
comprising a pH adjusting agent.

25. The aqueous formulation of claim 24 wherein the pH adjusting agent is
30 selected from the group consisting of hydrochloric acid, sodium hydroxide,
tromethamine, potassium hydroxide, and combinations thereof.

26. The aqueous formulation of any one of claims 1 through 25 further
comprising a buffer.

27. The aqueous formulation of claim 26 wherein the buffer is selected from the group consisting of citric acid, lactic acid, succinic acid, tartaric acid, and combinations thereof.

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28. The aqueous formulation of any one of claims 1 through 27 further comprising a preservative.

29. The aqueous formulation of claim 28 wherein the preservative is selected from the group consisting of benzalkonium chloride, benzethonium chloride, methylparaben, propylparaben, phenyl ethyl alcohol, and combinations thereof.

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30. The aqueous formulation of any one of claims 1 through 29 further comprising a chelating agent.

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31. The aqueous formulation of claim 30 wherein the chelating agent is ethylenediaminetetraacetic acid disodium salt dihydrate.

32. The aqueous formulation of any one of claims 1 through 31 further comprising a water-miscible cosolvent.

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33. The aqueous formulation of claim 32 wherein the cosolvent is selected from the group consisting of propylene glycol, glycerin, polyethylene glycol 400, diethylene glycol monoethyl ether, and combinations thereof.

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34. The aqueous formulation of claims 32 or 33 wherein the cosolvent is present in an amount of 5 wt-% to 15 wt-%.

35. An aqueous sprayable formulation comprising:

30 an immune response modifier selected from the group consisting of imidazoquinoline amines, tetrahydroimidazoquinoline amines, imidazopyridine amines, 6,7-fused cycloalkylimidazopyridine amines, 1,2-bridged imidazoquinoline amines, imidazonaphthyridine amines, imidazotetrahydronaphthyridine amines, oxazoloquinoline amines,

thiazoloquinoline amines, oxazolopyridine amines, thiazolopyridine amines, oxazonaphthyridine amines, thiazolonaphthyridine amines, 1*H*-imidazo dimers fused to pyridine amines, quinoline amines, tetrahydroquinoline amines, naphthyridine amines, or tetrahydronaphthyridine amines, and combinations

5 thereof;

water; and

a hydrophilic viscosity enhancing agent selected from the group consisting of cellulose ethers, polysaccharide gums, acrylic acid polymers, and combinations thereof;

10 with the proviso that the hydrophilic viscosity enhancing agent is not covalently bonded to the immune response modifier;

wherein the formulation is a solution at room temperature and has a viscosity of less than 100 cps at room temperature.

15 36. A method for delivering an immune response modifier to a nasal passage of a subject, the method comprising:

selecting a formulation comprising:

an immune response modifier;

water; and

20 a hydrophilic viscosity enhancing agent;

with the proviso that the hydrophilic viscosity enhancing agent is not covalently bonded to the immune response modifier;

wherein the formulation is a solution at room temperature and has a viscosity of less than 100 cps at room temperature; and

25 applying the selected formulation into a nasal passage or a subject.

37. A method of treating and/or preventing allergic rhinitis, the method comprising applying the formulation of any one of claims 1 through 34 into a nasal passage or a subject.

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38. A method of treating and/or preventing allergic rhinitis, the method comprising spraying the formulation of claim 35 into a nasal passage of a subject.

39. A method of treating and/or preventing a viral infection, the method comprising applying the formulation of any one of claims 1 through 34 into a nasal passage or a subject.
- 5 40. A method of treating and/or preventing a viral infection, the method comprising spraying the formulation of claim 35 into a nasal passage of a subject.
41. A method of treating and/or preventing sinusitis, the method comprising
10 applying the formulation of any one of claims 1 through 34 into a nasal passage of a subject.
42. A method of treating and/or preventing sinusitis, the method comprising spraying the formulation of claim 35 into a nasal passage of a subject.
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43. A method of treating and/or preventing asthma, the method comprising applying the formulation of any one of claims 1 through 34 into the respiratory tract of a subject.
- 20 44. A method of treating and/or preventing asthma, the method comprising spraying the formulation of claim 35 into the respiratory tract of a subject.
45. A method of desensitizing a subject to an antigen comprising:
administering to the subject an IRM compound in the formulation of any
25 one of claims 1 through 34, after the subject has been sensitized to the antigen, in an amount effective to desensitize the subject to the antigen.
46. The method of claim 45 wherein the IRM compound is administered to the subject at least four hours prior to re-exposure of the subject to the antigen.
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47. A method of desensitizing a subject to an antigen comprising:
administering to the subject an IRM compound in the formulation of claim 35, after the subject has been sensitized to the antigen, in an amount effective to desensitize the subject to the antigen.

48. The method of claim 47 wherein the IRM compound is administered to the subject at least four hours prior to re-exposure of the subject to the antigen.